



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,119	08/25/2003	Michael R. Violante	32286-192289	9829
26694	7590	05/23/2006	EXAMINER	
VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20045-9998				JAWORSKI, FRANCIS J
			ART UNIT	PAPER NUMBER
			3768	

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/647,119	VIOLANTE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Jaworski Francis J.	3737

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 11/25/03 IDS.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1 - 19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 - 19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 25 August 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All
  - b) Some \*
  - c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/25/03</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terminology 'open structures' is vague and indefinite in its context relationship to overcoating. With respect to for example foam materials the terms might relate to open versus closed cell structure, with an 'open' structure being 'sponge-like- i.e. connected to the exterior of the surface within which the cells reside. In this context the base claim language would pertain to an echogenic surface having inter alia an open cell structure which would freely communicate with the exterior but for the overcoating entrapping (generated) gas into sequestered voids. Claim 3 is consistent with such interpretation, namely that all such structures are one or more from a combination of structures which have a communicating aperture – pore, channel, cavity, pocket or combination thereof. However claim 10 makes back-reference to 'the entrapped gas bubbles' (for which antecedence is strictly lacking) yet which inferences that the 'open structures' of claim 1 might refer to trapped gas bubbles alone which, being open (no encapsulation enclosure) as entities i.e. as volume units of pure, evolving gas would be confined from coalescing or escaping and might be construed as being, becoming or leaving as open

structures in the process except for confinement by the overcoat. Therefore the scope of the base claim is unclear.

Dependent claims variously inherit the defect.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 – 7, 10, 12 – 13, 16 – 19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 8, 24, 38 - 40 of U.S. Patent No.6106473 and claims 1, 12 of US.6610016. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the 'overcoat' containment feature and the 'open structure'/non-compressibility features are claimed in the respective claim sets such that the claimed structure in this

Art Unit: 3737

application would have been obvious over the claims of the one patent in view of the other patent or vice-versa.. A contrast agent constitutes a 'pharmaceutical'. Otherwise the trapping structures which range in size from .1-300 microns would be expected to correlate with coating thicknesses in order of magnitude. Otherwise '016 claim 12 tracks this application's claim 12. Otherwise known film producing materials were heretofore claimed in '473 claim 24 such that these would at least be auspiciously suspect for forming a wettability reducing (barrier) overcoat. Otherwise claim 40 of '016 as dependent from claim 1 intimates a fabrication method of overcoating of a surface having open, gas-entrapping structures. Otherwise the aforementioned claimed device applications are inferential of the long term monitoring associated with the respective device.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Art Unit: 3737

Claims 1- 3, 5, 10, 12, 16, 19 are rejected under 35 U.S.C. 102(e) as anticipated by Partika (US5383466). Partika is directed to an ultrasonically visible surgical biopsy needle device insertable into a bodily target and having echogenic surfaces comprising open-structured bubbles and cavities (col. 2 line 41) covered over by the thin polymer matrix characterizable as a film which coats over and confines the bubbles. Since col. 4 lines 20-39 touts the fact that the bubbles must be retained as spherical even if microscopic, this would inherently mean that the bubbles are not being compressed or distorted from their native shape. Otherwise the polymer matrix is stated to provide mechanical anchoring together with an undercut instrument construct soas to provide a uniformly smooth outer contour.

[Note that whereas Partika does not specifically claim 'open structures' they do claim 'cavities...' in col. 2 line 41 which applicants' include as variants of open structures per claim 3. This point is related to the 112 2d para rejection lodged supra.]

Otherwise, reduced wettability inherently follows from a hardened polymer coat designed to retain the bubbles against resorption. Otherwise under the cavity – open enclosure interpretation the hardening in Partika necessarily involves formation of an entrapment/containment overcoating to the foam matrix proper.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

Art Unit: 3737

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partika in view of Rammler (US5327891) since whereas the former is silent as to particular polymers suitable for entraining the microbubbles within the coat, it would have been obvious in view of the latter col. 3 lines 21 – 26 that polyethylene is a suitable biocompatible entrainment material since it is used in an analogous in-vivo medical instrument for echogenicity purposes. Otherwise the Rammler device delivery suggestion implies a degree or period of device stationarity within the patient.

#### ***Allowable Subject Matter***

Claims 8 – 9, 11, 14 - 15 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Art Unit: 3737

The following art of ineffective date versus applicants' provisional application priority date and/or parent case dates is cited as of interest: Joseph (US6,306,094), Koulik (US7,014,610), Zhang et al (US6577904), Jones et al (US6506156).

Any inquiry concerning this communication should be directed to Jaworski Francis J. at telephone number 571-272-4738.



Francis J. Jaworski  
Primary Examiner  
Primary Examiner

FJJ:fjj

032106